Public Health Scotland

Guidance on vaccine storage and handling

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NHS National Services Scotland

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1	March 2023	Created in PHS template and made fully accessible.

Contents

1. Introduction

1.1. Aim and scope of the guidance

This guidance sets out a framework outlining the minimum standards that are required for effective storage and handling of vaccines thereby minimising the risk of compromising the effectiveness of vaccines given to patients. This document updates the guidance on vaccine storage and handling issued by Public Health Scotland in 2017 and supplements the recommendations in Chapter 3 of Immunisation against Infectious Disease 2006 (**the Green Book**).

The guidance is aimed at all staff involved with the planning or delivery of immunisation programmes in all settings. The purpose of this guidance is to support NHS Boards by providing a framework within which NHS Boards are expected to align their local policies regarding vaccine storage and handling.

1.2. Background information

The success of any immunisation programme depends upon the use of effective vaccines. All vaccines should be stored, handled, transported and administered in accordance with the manufacturer's instructions. Vaccines will lose their effectiveness over time and any storage outside the manufacturer's recommended range will speed up this loss. Loss of effectiveness is cumulative and irreversible.

Inappropriate vaccine storage can be serious, has the potential to present a public health problem and constitutes a risk to patient safety. Vaccines that are not stored and transported in accordance with the manufacturer's instructions may result in the failure of the vaccine to protect and, in extreme circumstances, may require individuals to be revaccinated. Vaccines are expensive and can be in short supply. Inappropriate storage and handling of vaccines can result in vaccine wastage which causes a financial loss for the NHS and can increase pressure on vaccine supplies.

The **Promoting Effective Immunisation Practice e-learning programme**, a collaboration between Public Health Scotland and NHS Education for Scotland (NES), is an educational

resource on immunisation for health professionals in Scotland. The programme has a module on storage and handling of vaccines.

2. The cold chain – what it is and why it is important

The cold chain is the name given to the system of transportation and storage of vaccines while maintaining the manufacturer's recommended temperature range, most often between +2°C and +8°. However, some vaccines do require storage in frozen conditions. Once these vaccines are removed from the freezer in the vaccine holding centre, the thawed vaccines can then be stored between+2°C and +8°C in accordance with the individual manufacturers' recommended storage conditions.

It is essential to maintain an unbroken cold chain from the point of vaccine manufacture, through transportation to distribution companies, storage in a refrigerator, cold room or freezer in a pharmacy, to transport to clinical settings where vaccines are stored in a refrigerator until they are used.

Heat speeds up the decline in potency of most vaccines. For the majority of vaccines, freezing can cause loss of vaccine effectiveness, increased local reaction at the injection site and systemic symptoms, and hairline cracks in the container, with cracks leading to contamination of the contents. It is, therefore, important that manufacturers' storage recommendations are always followed.

Effectiveness cannot be guaranteed for vaccines unless they have been transported, handled and stored at the correct temperature and in accordance with manufacturers' marketing authorisation.

Cold chain maintenance has three main components: equipment used for transport and storage, appropriately trained personnel and robust procedures. All three elements must combine to ensure that vaccine effectiveness is maintained by ensuring the vaccine is transported and stored at the recommended temperature up to the point that the vaccine is administered.

The maintenance of the cold chain is therefore important to:

- give assurance/confidence in potency of vaccine

- ensure maximum effectiveness/clinical benefit from immunisation
- minimise risk to vaccine effectiveness from extremes of temperature and inappropriate handling
- ensure compliance with manufacturer's marketing authorisation
- minimise financial loss and pressure on vaccine supplies from vaccine wastage

3. Key principles of vaccine storage and handling

3.1. Introduction

It is the responsibility of all healthcare professionals involved with the transport, handling, storage and administration of vaccines to ensure they understand the importance of maintenance of the cold chain. In each site where vaccines are stored or used the manager with overall responsibility for vaccine storage and handling should ensure there are written standard operating procedures (SOPs) in place and that all staff can demonstrate competence in accordance with this guidance. These SOPs should include information on the following aspects of vaccine storage and handling:

- Ordering
- Receipt
- Storage
- Stock rotation
- Transportation
- Monitoring refrigerator, cold room, freezer temperatures
- Action to take in the event of cold chain breach

These SOPs should be reviewed and approved at least every two years by the appropriate manager. (See specimen SOP – Appendix 1.)

In each site where vaccines are stored or used, there should be a designated person with overall responsibility for vaccine storage and handling who should designate a member of staff to be the main vaccine responsible person and another member of staff should be identified as their deputy. The designated vaccine responsible person or their deputy will be responsible for ensuring:

- all vaccines are ordered, received into stock and handled correctly
- refrigerator, cold room and freezer temperatures are appropriately monitored
- any cold chain breaches result in appropriate action to resolve the issue and are documented and reported
- all staff involved with storage and handling of vaccines have access to SOPs, are appropriately trained and can demonstrate competence.

In all sites where vaccines are stored there should be an annual audit. A specimen audit checklist for use by all staff involved in vaccine storage and handling. (See Appendix 2.)

3.2. Ordering of vaccines

In all areas where vaccines are used there should be a SOP detailing the process for ordering vaccines. This should specify who is responsible for placing orders. All vaccines, with the exception of a small number of travel vaccines, should now be ordered from NHS Board vaccine holding centres using the standard order form used within the NHS Board.

Vaccine stocks should be monitored by the designated vaccine responsible person or their deputy to avoid over-ordering or under-ordering. Care should be taken when ordering vaccines, especially as certain vaccines are packaged in multiple pack sizes, multi-dose vials or may have a short expiry date. Incorrect ordering can result in wastage and unnecessary costs.

In frontline clinical settings there should normally be no more than two weeks' supply of vaccines at any time. This will be enough for routine provision. Best practice is to order small quantities on a regular, scheduled basis. Ordering should be done in enough time to ensure that there is always an adequate supply for vaccination clinics. The responsible person must always consider storage capacity before placing an order.

Excess stock may:

- increase the risk of vaccination with out-of-date vaccines
- increase wastage and the cost of disposal
- increase the likelihood of problems associated with over-packed refrigerators i.e. poor air flow, temperature elevation, potential freezing of refrigerators and poor stock rotation
- delay the introduction of new vaccines until local supplies have been used
- increase the cost of replacement of stocks if the refrigerator fails
- increase the pressure on the performance of refrigerators in periods of high demand, e.g. during the influenza vaccination season

3.3. Receipt of vaccines

All deliveries of vaccines must be handed to an authorised and appropriately trained recipient and not left unattended. On receipt, deliveries of vaccines should be dealt with immediately. They should be examined for leakage or other damage. The vaccines received should be checked against the order/delivery note and a signature provided to confirm receipt. All deliveries should be checked carefully at the time of receipt as vaccines cannot be returned later. Vaccine delivery notes should be retained in accordance with the **Scottish Government Records Management: NHS Code of Practice** (Scotland) (2012) (see section 5.5) and batch numbers and expiry dates should be recorded. Vaccines requiring refrigeration should be placed in the refrigerator immediately after checking and signing to accept delivery and should not be left at room temperature. Vaccines that require continued frozen storage or ultra-low temperature storage upon receipt should be processed and stored immediately in accordance with the manufacturer's instructions. All staff handling vaccines shipped in dry ice or involved in dry ice disposal must be appropriately trained in the handling and disposal of dry ice and the use of personal protective equipment (PPE) required to do so.

3.4. Rotation of stock

Vaccine stocks should be placed within the refrigerator/cold room or freezer so that stock with the shortest expiry date is used first. This may not always be the most recently delivered vaccine. Expiry dates must always be checked prior to supply/administration and, in addition to this, a routine expiry date check must be carried out on a monthly basis. This process must be documented in the vaccine refrigerator/cold room/freezer temperature logbook.

3.5. Transportation of vaccines to schools, outlying clinics and domiciliary visits

Vaccines requiring refrigeration must be transported to schools and outlying clinics and vaccination centres in a vehicle that has been validated and is monitored throughout the journey or in cool boxes that have been validated to maintain the temperature within the recommended range of +2°C to +8°C for the period of transport. If vaccines are being stored in schools prior to their use, they should be stored in a pharmaceutical refrigerator with temperatures being monitored as described in section 5.1.

Some new vaccines are sensitive to movement which can affect the efficacy of the vaccine and therefore, agitation of the vials should be minimised throughout this time. Care must be taken to place the cool box in the vehicle in such a way so that it remains upright and stable throughout the journey.

Some vaccines have restrictions on the number of times they can be transported and/or the duration of transportation. The manufacturer’s transportation instructions should always be followed when transporting vaccines.

All staff involved with transport and storage of vaccines in vaccine holding centres, schools, outlying clinics and vaccination centres should be appropriately trained and must ensure that the validated cool boxes are used in accordance with the manufacturer’s instructions to ensure the correct storage conditions for vaccines at all times. With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods and therefore it is good practice to consider periodic internal revalidation and replacement of cool boxes and cool packs. Domestic cool boxes must not be used.

Although the manufacturers of cool boxes provide validation of cold chain maintenance for their products, it is considered good practice to carry out internal validation of cool boxes twice yearly (winter and summer) to determine their effectiveness in maintaining the cold chain during the period of transit to the furthest destinations and also during the longest scheduled delivery route.

Validated cool boxes suitable for transport of vaccines are available from a number of suppliers within the national framework. See section 7. Where the purchase of validated cool boxes for the purpose of transport of vaccines is under consideration, advice should always be sought from the appropriate person in the NHS Board Vaccine Holding Centre.

When transporting vaccines, only the amount of vaccine necessary for each session should be removed from the refrigerator. These should be placed quickly into validated cool boxes and opening must be kept to a minimum. Cool boxes must be clearly labelled and sealed appropriately during transportation and at school vaccination sessions. Consideration could be given to use of tamper-evident seals during transportation and also to the use of additional temperature monitoring devices to provide evidence of cold chain maintenance.

If there are any unused vaccines left over at the end of a vaccination session, provided they have been stored in a validated cool box which has been used in accordance with the manufacturer's instructions, the vaccines can be returned to the vaccine refrigerator. It is good practice to label returned vaccines and use them at the earliest opportunity.

Cool boxes should not be situated in direct sunlight, near radiators or near other heat source e.g. under-floor heating.

3.6. Disposal of expired stock

Any out-of-date stock should be appropriately quarantined, disposed of and recorded in accordance with local and/or national pharmaceutical waste policy arrangements.

4. Storage of vaccines and the vaccine refrigerator/cold room/freezer

4.1. General requirements

Vaccines requiring refrigeration should be stored in their original packaging in a **pharmaceutical** refrigerator or cold room at a temperature between +2°C and +8°C and protected from light. Storage in the original packaging allows easy product identification, easy checking of batch numbers and expiry dates and the packaging offers some protection against temperature fluctuation.

Ideally the principle of ‘strive for 5’ should be adopted, as a temperature of +5°C gives a greater leeway for protection against fluctuations in temperature.

Food, drink and clinical specimens must not be stored in refrigerators/cold rooms/freezers used for vaccines or medicines.

There should be sufficient refrigerator capacity to store the maximum vaccine storage needs (including seasonal influenza vaccine).

Vaccines should be stored within a **pharmaceutical** refrigerator/cold room that is specifically designed for the purpose of storing vaccines or medicines. These are designed to provide a stable, uniform and controlled temperature throughout the unit. Vaccines should not be stored in a domestic refrigerator.

To support decisions about procurement of pharmaceutical refrigerators, a specification for a refrigerator suitable for storage of vaccines is detailed in Appendix 4. Please also refer to National Framework for Vaccine Equipment – see section 3.5.

With age, the risk of a refrigerator failing increases with an increased resultant loss of vaccines. Audit data from several NHS Boards suggest that the majority of cold chain incidents due to refrigerator failure occurred in refrigerators which were over five years old. Consideration should be given to a programme of replacement of older refrigerators before problems occur.

Cold rooms should be designed and constructed in accordance with an agreed specification by an established company using appropriate materials. The design of the cold room must allow air

to circulate between shelves. Any shelving installed should facilitate air circulation. The cold room must be of sufficient size to allow storage of all necessary materials and equipment. A safety door release switch, which can be activated in the event of an operator becoming trapped, must be installed inside the cold room. The cold room should have a light inside so that it cannot be turned off from outside with someone in it. The cold room should have an integral temperature monitoring system connected to the digital display, recording system and monitored alarm. The design of any new cold room should meet these requirements as a minimum and also consider installation of dual compressors/evaporators as a contingency within the same storage space.

Freezers and ultra-low temperature freezers, where used, must be suitable for storing vaccines and documented evidence of this capability must be obtained from potential suppliers. Specifications should be obtained as part of the procurement of new equipment and, if possible, other users of equipment contacted to ensure that it would be acceptable for the intended purpose. Contact your NHS Board Vaccine Holding Centre for advice. See also Section 7 Procurement of cold chain solutions.

Vaccines are prescription-only medicines and should be stored under locked conditions. Refrigerators/cold rooms/freezers should either be lockable or within a room that is locked when not occupied by a member of staff. When the refrigerator is not in use the key should be removed and held by the appropriate person as detailed in local procedures.

Storage temperatures in refrigerators, cold rooms and freezers

Storage condition	Temperature limits
Refrigerator	+2°C to +8°C
Cold room	+2°C to +8°C
Freezer	-15°C to -30°C
Ultra-low temperature freezer	-60°C to -90°C

Always check the manufacturer’s storage instructions to ensure correct storage temperature is used for individual vaccines requiring storage in a freezer or ultra-low temperature freezer. Other temperatures may apply depending on specific vaccine requirements.

4.2. Organisation of the refrigerator

Vaccines should be spaced evenly throughout the refrigerator to allow cool air to circulate around the vaccine packages. No more than two thirds of the internal volume for the refrigerator should be filled.

Vaccines should not touch the back or sides of the refrigerator to ensure adequate circulation of cool air. Manufacturers of refrigerators will usually provide guidance regarding the clearance required. If there is any doubt it is reasonable to leave an air gap of 4 cm between vaccines and the internal sides of the refrigerator.

Pharmaceutical refrigerators do not have storage compartments/shelves in the refrigerator door and refrigerators with these should not be used to store vaccines. Vaccines should not be stored in any integral enclosed plastic trays at the bottom of the refrigerator that may be found in some older style vaccine/pharmacy refrigerators. These prevent the circulation of cool air and may lead to warming of vaccines.

Vaccines should be organised within the refrigerator so that they can be found quickly and to minimise the length of time that the door is open. It is considered good practice to display a map on the door of the refrigerator listing the contents and their shelf location.

4.3. Power supply

Accidental disconnection from power source is a common reason for breaches of the cold chain. Where possible, the mains supply to the refrigerator should be directly wired (‘spurred’) into the electrical supply. Where this is not possible, arrangements should be put in place to ensure the plug is never pulled out and the switch is never turned off. (These arrangements could include difficult access to the socket, e.g. behind the refrigerator or physical cover).

No equipment or power supply is infallible, therefore, in all areas where vaccines are stored there should be contingency plans in the event of equipment failure. Such plans should consider the need for and location of back-up facilities and detail the actions required by individuals and their responsibilities. The use of continuous wireless temperature monitoring systems should be considered to provide early warning of fridge/freezer failure and provide live temperature data to assist in decisions regarding the relocation and continued use of affected vaccines.

Any switches that are used to connect refrigerators to the power supply should be clearly identified ‘Refrigerator – do not switch off’.

Vaccine refrigerators should not be switched off other than to clean and/or defrost the refrigerator, in the event of an electrical emergency or if the refrigerator is being worked on by an engineer. In these cases, the vaccine stock should be transferred to another appropriate pharmaceutical refrigerator or validated cool box. Vaccine refrigerators may be switched off temporarily (less than five minutes) in order to replace a faulty light bulb without the stock being moved but this should be noted on the refrigerator temperature record.

In the event of a power outage, refrigerator doors should be kept closed and the temperature monitored until either the supply is reinstated or alternative arrangements for storage can be made. It is important to document the time the power outage began and ended and also the duration of the cold chain breach, e.g. the time the vaccines were outside the manufacturer's recommended range and the maximum or minimum temperature recorded throughout, if known. A contingency plan should be in place for such eventualities. Each incident should be reported to the appropriate person in accordance with local NHS Board arrangements for guidance. Contact the local NHS Board for guidance if there is a planned time-limited power outage.

4.4. Placement of refrigerator

Refrigerators should not be situated in direct sunlight or near a radiator or other heat source. There should be adequate ventilation space around the refrigerator to allow free circulation of air to cool the compressor motor. Where possible, refrigerators should not be placed against an external wall as in some circumstances these may be subject to hot and cold temperatures with changes in weather.

4.5. Installation of a new refrigerator/movement of an existing refrigerator

When a new refrigerator has been installed, or where a refrigerator has been moved, it should be placed into the area where it will be used, ensuring that it is level, and left for a minimum of 24 hours before switching it on, as tilting refrigerators can affect the placement of the coolant within the compressor.

Where a refrigerator is switched on for the first time or after a prolonged period of time where it has been switched off, the refrigerator should be left to run for a period of time before it is used to store vaccines. There is no exact requirement stated by refrigerator manufacturers but good practice suggests that the refrigerator should be run for 48 hours with twice-daily checks of current, maximum and minimum temperature to ensure the unit is functioning correctly before it is used to store vaccines.

When a refrigerator has been switched off for a short period to undertake defrosting or as a result of a brief interruption in power supply, the refrigerator temperature should be allowed to stabilise within the recommended range (+2°C to +8°C) after it has been switched on before being used to store vaccines.

4.6. Cleaning the vaccine refrigerator/cold room/freezer

Refrigerators/cold rooms/freezers should be kept clean. Where routine cleaning is required, domestic detergent and water should be used. All cleaning solutions should be thoroughly rinsed off and care exercised to avoid damage to the unit. A record of when cleaning has been carried out should be made in the vaccine refrigerator temperature logbook. Vaccines should be transferred to another pharmaceutical refrigerator with appropriate monitoring of temperatures or validated cool box during cleaning. Any spillage of vaccines should be dealt with in accordance with NHS Board waste management policy.

The vast majority of pharmaceutical refrigerators now have automatic defrost functionality. However, where refrigerators do not have this function, they should continue to be defrosted in accordance with the manufacturer's instructions.

If you experience any issues with build-up of ice in a refrigerator with automatic defrost functionality, contact your NHS Board representative for advice.

4.7. Maintenance

All refrigerators/cold rooms/freezers should be maintained in line with the manufacturer's advice and should be in good condition (e.g. working keys, locks, door seals intact).

Portable appliance testing (PAT) should be undertaken in accordance with local arrangements.

The refrigerator/cold room/freezer door seals should be checked regularly to ensure a good seal is maintained.

Calibration and function of all temperature recording and monitoring devices, including alarms and other associated equipment, must be carried out on at least an annual basis. Calibration should be traceable to national standards e.g. United Kingdom Accreditation Service (UKAS).

4.8. Planned preventative maintenance

It is advisable to have a regular planned preventative maintenance (PPM) programme in place for routine maintenance and repair of vaccine refrigerators/cold rooms/freezers. The scope of the maintenance carried out may be dependent on the equipment installed and include, for example, checks on compressor performance, checks on refrigerant levels, temperature checks/temperature mapping and alarm performance checks. This is especially important for cold rooms where larger volumes of medicines may be stored. Guidance on maintenance requirements should be sought from the appropriate department within each NHS Board.

Additional information can be found in the Scottish Pharmacy Quality Assurance Group (SPQAG) document **Guidelines for the management, maintenance and monitoring of cold rooms, refrigerators and freezers used to store medicinal products** or by request from the Scottish Immunisation Programme via email at **phs.immunisation@phs.scot**.

4.9. Identification of the refrigerator/cold room/freezer

Each refrigerator/cold room/freezer used to store vaccines should be clearly identified, by a unique number or code (e.g. asset number) and this should be recorded in the vaccine refrigerator temperature logbook. The refrigerator model and serial number should also be documented in the temperature logbook.

It is not sufficient, for example, to identify it as ‘small refrigerator – doctors’ room’ as the use of the room may change or the refrigerator may be moved.

For all new refrigerators, the vaccine refrigerator temperature logbook should also contain the date at which the refrigerator was used for the first time.

5. Monitoring vaccine refrigerator performance and storage conditions

5.1. Monitoring refrigerator/cold room/freezer temperatures (daily temperature recording)

The person with overall responsibility for vaccine storage and handling or their deputy is responsible for ensuring all staff dealing with the storage of the vaccines and daily temperature recording are competent in reading and recording temperatures and resetting the maximum/minimum thermometer.

Where continuous, wireless temperature monitoring systems are used to record temperatures, the person with overall responsibility for vaccine storage and handling should ensure all staff dealing with the storage of the vaccines are competent in the process of checking the temperature data within the system.

In all areas where vaccines are stored there should be an SOP for monitoring/recording of refrigerator/cold room/freezer temperatures (including wireless temperature monitoring systems). Recording twice daily at the start and end of daily work sessions is recommended. However, the Green Book states that once-daily recording as a minimum is acceptable.
See specimen SOP for monitoring refrigerator performance and recording temperatures in Appendix 1.

The current, maximum and minimum temperatures should be recorded legibly and monitored twice a day. After each recording the thermometer memory should be reset. A standard temperature monitoring record should be used. A specimen temperature monitoring record is included in Appendix 2. Temperature records relating to a particular refrigerator should be kept close to that refrigerator (but not inside) for ease of reference and should be clearly identified as relating to that appliance. A separate temperature record should be kept for each refrigerator. Electronic records are acceptable provided they capture all of the recommended information and are stored on a system that has appropriate back up.

It is good practice to record the temperatures at a similar time each day, e.g. first thing in the morning before the refrigerator door is opened for the first time and just before leaving the site

at the end of the work session. This will allow review of trends in results recorded and help highlight any changes in temperatures recorded and deviation in refrigerator performance. Any trend of increasing or decreasing temperatures within the recommended range should be investigated before problems occur. The person checking the temperature should sign the recording sheet.

It is also good practice to record any activity which may affect the temperatures recorded, e.g. tidying, restocking, cleaning, at the time it takes place

5.2. Monitoring refrigerator/cold rooms/freezer temperatures (monthly check)

The person with overall responsibility for vaccine storage and handling is responsible for carrying out the following checks at the end of each month:

- Analyse manual temperature records and/or electronic temperature monitoring device (ETRD) data to identify trends and investigate problems before they occur
- Confirm from the temperature records that there is evidence that the thermometer is being reset
- Confirm that a review of expiry dates has been carried out
- Ensure all housekeeping tasks within the wireless temperature monitoring system are completed and that all alarms have been acknowledged.

5.3. The refrigerator thermometer

The refrigerator/cold room/freezer should be fitted with a thermometer capable of continuous monitoring to ensure that the temperature remains within the specified range of +2°C to +8°C.

For new vaccine refrigerators/cold rooms/freezers a calibrated digital thermometer will be provided in the form of an integral probe connected to a digital display. Where a calibration certificate is supplied by refrigerator manufacturers it should be retained as evidence of calibration.

Analogue devices are not acceptable. **The integral or independent refrigerator maximum/minimum thermometer should:**

- be able to be read from the outside of the refrigerator without opening the door
- record to one decimal place
- have an accuracy of at least +/- 1°C
- be supplied with a calibration certificate if available
- have its accuracy checked at least on an annual basis
- ideally be independent of mains power, so that temperatures can be measured in the event of electricity loss. (Please note, it is important to ensure that batteries are inserted and replaced in accordance with manufacturers' or NHS Board recommended timescales)

5.4. Resetting the thermometer

The person with overall responsibility for vaccine storage and handling must ensure that staff know how to reset the thermometer.

The maximum/minimum thermometer should be reset by clearing the thermometer memory after each reading. To ensure the reset has been carried out correctly, the maximum, minimum and current temperatures should be checked again and, if the thermometer has been correctly reset, these should all show the same (current) temperature.

It is good practice to reset the thermometer at the end of a clinic if the refrigerator door has been opened on several occasions or if the refrigerator has been restocked or cleaned. Resetting should be carried out once the current temperature reading has returned to within the recommended range.

If temperatures are noted to be outside the recommended range, then this should be recorded along with action taken to resolve the issue. For example, if cleaning the refrigerator has taken place or the door has been left open for a period of time, e.g. to restock the refrigerator, this should be recorded in the comments column.

Monitoring the refrigerator temperatures should be facilitated by using the ‘four Rs’:

- **Read**: reading of the thermometer’s maximum, minimum and current temperatures twice daily on all working days
- **Record**: recording temperatures in a standard fashion and on a standard form, including signing each entry on the recording sheet
- **Reset**: resetting the thermometer after each reading. The thermometer should also be reset when temperatures have stabilised after periods of high activity
- **React**: the person making the recording should take action if the temperature falls outside +2°C to +8°C and document this action

5.5. Retention of temperature records

Retention of records under the **Scottish Government Records Management: NHS Code of Practice** (Scotland) (2012).

Under 'Pharmacy records: quality assurance' it is recommended that refrigerator temperature records should be retained for the life of any vaccine stored therein with a minimum of a one-year retention period.

As shelf lives specified by vaccine manufacturers can be up to four years or longer, retaining records for five years will generally enable the full storage history of vaccines to be accounted for.

5.6. Checking the performance of the refrigerator/thermometer

Calibrated electronic temperature logging devices suitable for checking the performance of the refrigerator (temperature mapping) and refrigerator thermometer are available from a number of suppliers. Where the purchase or use of temperature logging devices is under consideration then advice should be sought from the appropriate person in the NHS board.

6. Action to be taken following recording of temperatures found to be outside the recommended range

‘One-off’ fluctuations in refrigerator temperatures rising above +8°C but lasting less than 20 minutes, such as may occur when stocktaking or restocking, are not likely to have breached the vaccine cold chain and as such do not require further action. The cause of the ‘excursion’ should be documented on the temperature recording chart, the maximum/minimum thermometer reset, where used, and vaccines continued to be used to their expiry date.

In the event of a significant cold chain breach or an inadvertent or unavoidable deviation of these conditions, refer to the **UK Health Security Agency (UKHSA) Vaccine incident guidance**. This document is intended to be used by a wide range of healthcare professionals with a role in delivering immunisation programmes, in the investigation and management of vaccine storage or administration incidents.

Scottish Health Protection Network (SHPN) has produced an **addendum to the UKHSA Vaccine incident guidance.**

If temperatures outside the recommended range (+2°C to +8°C) are identified for longer than 20 minutes, the following actions should be taken:

- Consider whether this has implications for the cold chain storage of current and recently administered vaccine stock
- Consult the appropriate contact in the NHS Board to ensure that a risk assessment of the impact of temperatures on the affected vaccines is undertaken
- Make the servicing of the refrigerator a priority

A procedure should be available to describe the actions that should be taken in the event of the temperature going outside the recommended range (+2°C to +8°C). The person with overall responsibility for vaccine storage and handling or their deputy should be informed, and a note of any action taken or comments on temperatures outside the +2°C to +8°C range should be clearly made on the temperature recording log. **It is important to review action taken to ensure an appropriate outcome.**

Reasons for readings being out of the recommended range may include:

- the refrigerator door being left open
- restocking
- unplugging of the refrigerator from the power socket or other loss of power
- malfunction or failure of the refrigerator or thermometer

If there are any concerns about the storage of the vaccine and subsequent viability, the suspect stock should be quarantined and kept within a suitable pharmaceutical refrigerator but must not be destroyed until further investigation and risk assessment has been completed by NHS Board staff. Advice should be sought from the designated contact in the NHS Board. A system of notifying local staff with responsibility for vaccines should be in place. An incident/record form should be completed using NHS Board standard operating procedures for incident reporting.

The following checklist provides a framework for the essential steps that should be taken in the event that the recorded maximum and/or minimum temperature is outside the recommended range of +2°C to +8°C.

- The person noting the temperature should inform the person with overall responsibility for vaccine storage and handling or their deputy and/or the appropriate manager
- The cause should be immediately investigated and, where possible, the problem should be rectified
- Assess the period of time the products are exposed to a temperature outside the recommended range
- Place affected stock into quarantine but keep stock in a refrigerator – transfer to another refrigerator if possible
- Record the details of products that are affected; vaccine name, brand, batch numbers, expiry dates, quantity and if national campaign stock
- Assess if any vaccine stocks have been subjected to previous temperature excursions
- Discuss with the designated contact in the NHS Board to request a risk assessment be carried out and obtain advice regarding whether stock can be used

- Assess the implications for stock and arrange for further supplies to meet immediate clinical need
- Ensure action is taken to prevent/reduce the risk of recurrence of problem
- Document all actions

7. Procurement of cold chain solutions

A National Framework for NHS Scotland is available covering:

- calibrated pharmacy refrigeration equipment (+2°C to +8°C)
- validated vaccine cool boxes and transport solutions
- supporting equipment and devices including wireless temperature monitoring systems and electronic temperature recording devices and so on.

The National Framework is managed by National Procurement and initial queries/requests for information should be directed to **nss.e-fcategory@nhs.scot**

Appendix 1: Specimen standard operating procedure (SOP) for monitoring refrigerator performance and recording temperatures

Example standard operating procedure

Item	Details
Vaccination centre/unit name	
Person responsible for vaccine storage and handling	
Deputy	
SOP number	
SOP title	Temperature recording and checking procedure
SOP title	Temperature recording and checking procedure
Page(s)	
Written by (name)	
Written by (signature)	

Item	Details
Approved by (name)	
Approved by (signature)	
Date approved	
Review date	

Appliance details

Appliance identification	Appliance location	Use and limits	Fitness for purpose review
		Vaccine storage at +2°C to +8°C	Twice daily on all working days

Standard limits

Refrigerator temperature +2°C to +8°C.

Procedure

1. At the start of each month, a new record sheet should be used for each appliance. (A vaccine refrigerator temperature logbook is required for each appliance.)
2. Twice-daily, preferably at the start and end of the working session, the maximum/minimum thermometer is read, and the maximum temperature, minimum temperature and current temperature are recorded along with the date and time.
3. Each entry should be checked to ensure that all three temperatures are within the +2°C to +8°C range.

4. Note any cleaning or restocking activities which may have been undertaken and which may have a potential to affect refrigerator performance.

5. If all readings are within the range, then the person recording signs the entry and no further action is needed.

6. If any part of the entry is out of range, then the person recording should try to identify any reason that could explain the discrepancy and they should bring it to the attention of the designated vaccine responsible person and/or manager of the clinic/department/ vaccination centre.

7. If there is any doubt about whether the contents may have been compromised due to inappropriate storage conditions, quarantine the stock but continue to keep it under the correct refrigeration conditions. Check as soon as possible with an appropriate person, e.g. Supplying pharmacy on telephone [add number here].

8. Record any reason for the discrepancy, any advice given and the expert source consulted.

9. Record any action taken and sign the log sheet.

10. On each occasion, after the temperatures have been recorded, the maximum/minimum thermometer should be reset following the manufacturer's instructions.

11. The designated vaccine supervisor should review the temperature records on a monthly basis ensuring that:

    - the temperatures are within the recommended range
    - there is evidence that the thermometer has been reset on each occasion
    - expiry date checks have been carried out
    - the above processes are documented appropriately

Appendix 2: Vaccine storage and handling specimen audit checklist

The purpose of this audit checklist is to provide a tool to assess the arrangements for the storage and handling of vaccines in any areas/sites where vaccines are stored in order to identify areas where improvement is necessary.

A separate audit checklist should be used for each of the refrigerators used to store vaccines.

Any areas of concern should be discussed with the manager in charge of the area/site.

Where any issues are identified these should be discussed where required with the appropriate person in the NHS Board and remedial action undertaken.

Audit checklist – general

Question	Answer
Audit undertaken by (name and designation 1)	
Audit undertaken by (name and designation 2)	
Site being audited?	
Date of audit?	
Location of refrigerator?	
Refrigerator identification number?	
Manufacturer/model?	
Approximate age (years)?	

Audit checklist – Section 1 – People

Question	Answer
Who is the designated person in charge of monitoring the storage and handling of vaccines (name and designation)?	
Who is the named deputy for the designated person (name and designation)?	

Audit checklist – Section 2 – Procedures/training

Statement	Answer (Yes or No)	Comment
There is a vaccine storage and handling protocol in place that provides evidence that all staff have access to information regarding NHS Board guidance/policy for handling/storage of vaccines		
There is a vaccine storage and handling protocol in place that provides evidence that all staff involved with the handling of vaccines have been trained appropriately in maintenance and monitoring of the cold chain		
All staff involved with the handling of vaccines have been trained appropriately in maintenance and monitoring of the cold chain		
There are standard operating procedures for ordering vaccines		

Statement	Answer (Yes or No)	Comment
There are standard operating procedures for receipt of vaccines (including handling dry ice and dry ice disposal)		
There are standard operating procedures for rotation of vaccine stock and checking expiry dates		
There are standard operating procedures for daily temperature monitoring/recording		
There are standard operating procedures for review of temperature records on a monthly basis		
There are standard operating procedures for transportation of vaccines while maintaining the cold chain		
There are standard operating procedures for action, documentation and reporting of incidents following recording of temperatures outside the recommended range for more than 20 minutes		
There are contingency plans in place in the event of equipment failure and staff are aware of plans		
There is evidence that all staff involved with the handling of vaccines have read and understand the procedures		Record of acknowledgement

Statement	Answer (Yes or No)	Comment
Procedures are reviewed at least annually		

Audit checklist – Section 3a – Equipment – The vaccine refrigerator

Statement	Answer (Yes or No)	Comment
There is evidence that the pharmaceutical refrigerator used to store vaccines **is locked when not in use and the key is removed and/or within a room that is locked when not occupied**		Keys must be stored safely
There is evidence that the pharmaceutical refrigerator used to store vaccines **is in good condition – including locks, keys, door seals, shelving**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **is only used for storage of vaccines and medicines and is filled to no more than two thirds of the internal volume**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **has a fan that is unobstructed**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **has no vaccines stored in enclosed**		

Statement	Answer (Yes or No)	Comment
plastic trays throughout or at the bottom of the refrigerator		
There is evidence that the pharmaceutical refrigerator used to store vaccines **has vaccines organised in a way that allows quick access and minimises the time that the refrigerator door is open**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **is directly wired (spurred) or all plugs are clearly marked 'refrigerator: do not switch off' or are physically covered**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **is situated away from heat sources and direct sunlight**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **has adequate ventilation space around the refrigerator**		
There is evidence that the pharmaceutical refrigerator used to store vaccines **has an auto defrost function**		
There is evidence that the pharmaceutical refrigerator used to store vaccines is cleaned regularly		

Audit checklist – Section 3b – Equipment – The refrigerator thermometer

Statement	Answer (Yes or No)	Comment
There is evidence that **the thermometer is integrated into the refrigerator with a digital temperature display to one decimal place**		
There is evidence that **the thermometer is capable of recording the current, maximum and minimum temperatures**		
There is evidence that **the digital thermometer is capable of recording temperatures and can continue to record data during power/mechanical failure of the refrigerator**		
There is evidence that **in case of independent maximum/minimum digital thermometer the probe is placed in the middle of the refrigerator unobstructed**		
There is evidence that **other devices are used to record temperatures during power/mechanical failure of the refrigerator – SD card**		
There is evidence that **other devices are used to record temperatures during power/mechanical failure of the refrigerator – data logger**		
There is evidence that **other devices are used to**		

Statement	Answer (Yes or No)	Comment
record temperatures during power/mechanical failure of the refrigerator – other		
There is evidence that **the calibration of the thermometer or temperature monitoring devices is checked at least on an annual basis**		

Audit checklist – Section 4 – Temperature monitoring/recording

Statement	Answer (Yes or No)	Comment
There is evidence that **a separate record is used for each refrigerator**		
There is evidence that **the current, maximum and minimum temperature has been recorded twice a day on working days**		
There is evidence that **the temperature record is kept close to the refrigerator**		
There is evidence that **the thermometer is reset after each reading**		
There is evidence that **the daily temperature records are signed by the person taking the reading – legible**		
There is evidence that **information about activity**		

Statement	Answer (Yes or No)	Comment
such as restocking/cleaning the refrigerator etc that may affect temperature is recorded		
There is evidence that **the vaccine supervisor has signed to indicate that they have reviewed the temperature records on a monthly basis, and the temperatures are within range**		
There is evidence that **the vaccine supervisor has signed to indicate that there is evidence that the thermometer has been reset on each occasion**		
There is evidence that **the vaccine supervisor has signed to indicate that expiry date checks have been carried out**		
There is evidence that **the vaccine supervisor has signed to indicate that the above processes are all documented appropriately**		
There is evidence that **any readings outside the recommended range have resulted in documented action to resolve the issue**		
There is evidence that **temperature records are**		

Statement	Answer (Yes or No)	Comment
retained in accordance with guidance		

Appendix 3: Specimen temperature record

This template can be adapted for use with freezers/ultra-low temperature – see section 4.1 for storage conditions and temperature limits.

Vaccination Centre/ward	Refrigerator location	Month and year	Appliance number

The temperature should be maintained between +2°C and +8°C

If the temperature is outside this range, report immediately to the designated vaccine supervisor

Date	Time	Current temp. (+2°C to +8°C)	Minimum temp. (+2°C to +8°C)	Maximum temp. (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max./min. thermometer memory cleared and checked (initial)	Signature
Example row	**Example row**	**5.1°C**	**3.2°C**	**7.3°C**	**Tidying stock**	**AN**	**A Nurse**
1							
1							
2							
2							

Date	Time	Current temp. (+2°C to +8°C)	Minimum temp. (+2°C to +8°C)	Maximum temp. (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max./min. thermometer memory cleared and checked (initial)	Signature
3							
3							
4							
4							
5							
5							
6							
6							
7							
7							
8							
8							
9							
9							
10							
10							
11							
11							
12							
12							
13							
13							
14							

Date	Time	Current temp. (+2°C to +8°C)	Minimum temp. (+2°C to +8°C)	Maximum temp. (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max./min. thermometer memory cleared and checked (initial)	Signature
14							
15							
15							
16							
16							
17							
17							
18							
18							
19							
19							
20							
20							
21							
21							
22							
23							
23							
24							
24							
25							
25							
26							

Date	Time	Current temp. (+2°C to +8°C)	Minimum temp. (+2°C to +8°C)	Maximum temp. (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max./min. thermometer memory cleared and checked (initial)	Signature
26							
27							
27							
28							
28							
29							
29							
30							
30							
31							
31							

The designated vaccine supervisor should review the temperature records on a monthly basis ensuring that:

- the temperatures are within range
- there is evidence that the thermometer has been reset on each occasion
- expiry date checks have been carried out
- the processes are documented appropriately

Recordings for the month reviewed by:

Date:
Signature:

Appendix 4: Specification for a vaccine refrigerator

The following is a specification of the features that should be considered when procuring a new vaccine (medicines) refrigerator:

A number of suppliers will supply a pharmaceutical refrigerator for storage of vaccines/medicines which should meet the following criteria.

The following criteria are viewed as essential:

- Maintains internal air temperature between +2°C and +8°C – adjustable default/range/alarm set points – clear instructions on adjustment of refrigerator set/alarm points should be provided
- Forced air cooling, i.e. fan assisted
- CFC and HCFC-free refrigeration system and insulation
- Audio/visual local alarm signal on temperature deviation, ideally with remote alarm terminals providing mains failure alarm signal
- Digital temperature display with maximum/minimum memory for continuous monitoring
- Have a thermometer with an accuracy of at least +/- 1°C
- The thermometer is independent of mains power such that measurement of temperature is possible in the event of mains power loss
- Supplied with a calibration certificate
- Lockable solid door for security
- Wire shelves/baskets or shelves capable of allowing air ventilation
- Fully automatic defrosting

The following features may also be considered:

- Designed for efficient and effective operation in high ambient temperatures

- Adjustable feet for levelling and rear roller for easy positioning (lockable)
- Glass door
- Internal illumination
- Wall mounting brackets (for small vaccine refrigerators)
- Continuous temperature recording devices with autodialler/text function

General points such as power requirements, heat output, fan/refrigerator noise, size, weight, ease of cleaning should also be considered, as with the purchase of any equipment.